

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	
<hr/>		CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
ALL CLASS ACTIONS	)	
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ABBOTT LABORATORIES' SEPARATE  
REPLY IN SUPPORT OF ITS MOTION TO DISMISS  
PLAINTIFFS' AMENDED MASTER CONSOLIDATED COMPLAINT

**I. Plaintiffs Do Not Explain How AWP Manipulation Can Create Competitive Advantage for the Brand Name Abbott Drugs Named in the AMCC**

Plaintiffs' theory of "AWP manipulation" does not hold true for the brand name Abbott drugs named in the AMCC, none of which is alleged to be covered by Medicare Part B.

Plaintiffs' theory of AWP manipulation is based on *brand name drugs covered by Medicare Part B.* Plaintiffs contend that, for these drugs, manufacturers gain a competitive advantage by raising AWPs. This theory requires three elements to apply to a drug:

1. A competitive, therapeutic equivalent must exist.
2. The provider who chooses the drug must receive payment directly.
3. The payment for the two competing drugs must be based upon each drug's individual AWP. *See* 42 C.F.R. § 405.517(b).

Under these circumstances, plaintiffs argue, a manufacturer can increase the "spread" between AWP and acquisition cost to create an incentive for the provider to choose a drug over its competitor. This is the alleged "fraudulent scheme" on which the MCC and the AMCC have been based. Plaintiffs do not allege that the Abbott brand name drugs named in the AMCC are covered by Medicare Part B, or that they otherwise are paid in this manner.<sup>1</sup>

Plaintiffs' paradigm does not necessarily apply to *brand name drugs in the private payor context.* Depending on the circumstances under which the private entity pays for those drugs, some or all of the factors described above may not exist. For example, if a physician prescribes the drug but does not receive payment directly, no motive exists to choose the drug with the higher "spread." Similarly, if payment does not depend upon individual AWPs, competition based on raising AWPs is not possible.

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<sup>1</sup> Plaintiffs concede that they cannot maintain Medicare-based claims as to Biaxin<sup>®</sup>, Depakote<sup>®</sup>, Ery-Tab, Erythromycin and Prevacid<sup>®</sup>. *See* Pl. Sep. Mem. 19.

Unlike Medicare, the Court cannot look to regulations to determine how payment amounts are calculated in the private sector. Instead, the Court must rely on the allegations in the complaint. Plaintiffs, however, fail to explain how they and other private entities pay for the drugs named in the AMCC. Moreover, plaintiffs do not name any competitor against which Abbott's brand name drugs can compete on the basis of AWP.<sup>2</sup> Thus, as explained in TAP Pharmaceutical Products Inc.'s individual reply, claims relating to such drugs must be dismissed.

**II. Plaintiffs Do Not Explain How AWP Manipulation Can Create Competitive Advantage for the Multiple-Source Abbott Drugs Named in the AMCC**

Plaintiffs' theory still does not apply to *multiple-source drugs covered by Medicare*

**Part B.** In that context, the third factor identified above does not exist: As a matter of law, Medicare pays at a flat rate, and not based on each drug's individual AWP. *See* 42 C.F.R. § 405.517(c). No competitive advantage can be gained by manipulating AWP for these drugs.

Similarly, if a *multiple-source drug in the private payor context* is paid at a flat rate, AWP manipulation is not possible. According to the AMCC, private payors often establish a "Maximum Allowable Cost" or "MAC" for a multiple-source drug, paying all formulations at a single rate. *See* AMCC ¶ 181. When that is the case, the third factor described above again is not satisfied. As with brand name drugs, plaintiffs have not described their own payment rules for each of the multiple-source drugs named in the AMCC, much less the rules applied by other private payors. Consequently, this Court cannot conclude that AWP manipulation is possible for these specific drugs in the private payor context, and plaintiffs' claims must be dismissed.

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<sup>2</sup> Plaintiffs' facetious identification of competitors in their opposition is not sufficient. *See* Pl. Sep. Mem. at 20. First, those allegations are not found in the AMCC. Second, the mere identification of competitors is inadequate without an explanation for how those drugs compete *based on the AWP "spread."* *See* Abbott Mem. 5.

### **III. Plaintiffs Allege No “Fraudulent AWP” for Eight Abbott Drugs**

Plaintiffs do not allege a “fraudulent AWP for each drug” as required by this Court’s May 13 Order. *AWP Litigation*, 263 F. Supp. 2d at 194. As to seven Abbott products, plaintiffs identify no so-called “spread.” As to Liposyn II, the AMCC does not identify any AWP.<sup>3</sup>

According to plaintiffs, the purpose of alleging a “fraudulent AWP” for each drug in the AMCC is “to clearly identify . . . the fraud being perpetrated by Defendants *with respect to the designated drugs.*” Pl. Sep. Mem. at 8 (emphasis added). Plaintiffs argue that to meet that requirement they are “not required to plead the actual spread” for every drug. *Id.* at 18. Instead, they contend, it is enough to describe “examples of AWP fraudulent inflation.” *Id.* at 7. As to these eight Abbott drugs, however, the supposed “examples” do not relate to the products named. For these drugs, plaintiffs allege only that Abbott manufactured the drugs and that an AWP was published for them. That is not sufficient to satisfy the Court’s May 13 Order or Rule 9(b).

### **IV. Claims Regarding Products Paid on a Non-AWP Basis Should Be Dismissed**

Plaintiffs concede that Aminosyn and Liposyn II claims have never been paid on the basis of AWP, suggesting instead that “reasonable charges” might be set based on AWP. *See* Pl. Sep. Mem. 19. This connection between AWP and “reasonable charges” is not supported by law and is not alleged in the AMCC. Accordingly, claims as to these products should be dismissed.

### **V. Conclusion**

For the foregoing reasons, as well as those stated in the consolidated reply, the Together Rx reply and those individual defendants’ replies that apply to Abbott, this Court should dismiss the Amended Master Consolidated Complaint as to all Abbott drugs.

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<sup>3</sup> Contrary to plaintiffs’ suggestion, Abbott did not concede that plaintiffs have identified fraudulent AWPs for the other eighteen Abbott drugs identified in the AMCC. *See* Abbott Mem. at 3.

Respectfully Submitted,

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